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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,926	07/05/2000	AKIRA SAIKAWA	2500USOP	4424

23115 7590 10/08/2002

TAKEDA PHARMACEUTICALS NORTH AMERICA, INC
INTELLECTUAL PROPERTY DEPARTMENT
475 HALF DAY ROAD
SUITE 500
LINCOLNSHIRE, IL 60069

EXAMINER
LUKTON, DAVID

ART UNIT	PAPER NUMBER
1653	9

DATE MAILED: 10/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/582,926	SAIKAWA ET AL.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for R ply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *17-20 and 24-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Pursuant to the directive of paper No. 8, claim 28 has been cancelled. claims 1-27 remain pending.

Applicants' election of Group 6 (claims 1-16, 21-23 and 28, wherein a biodegradable polymer must be present) is acknowledged, as are the elected species:

(a) the "biologically active substance" is the following

5-oxo-Pro-His-Trp-Ser-Tyr-D-Leu-Leu-Arg-Pro-Gly-NHEt

(b) a polymer of lactic acid in which glycolic acid is absent, and the molecular weight is in the range of 3-100K;

(c) 3-hydroxy-2-napthoic acid as the specific hydroxynapthoic acid.

. . . .

Applicants are advised that the preliminary amendment has not been entered. This amendment directs several changes, including the following:

On page 1, insert - - and - - ; on page 2, replace "the" with - - a - - at two locations; on page 4, delete "of", and on page 6, delete "a".

However, the changes directed are numerous, and moreover many of them require the insertion or deletion of single words. Given the nature of the requested amendment, it has not been entered. Should applicants deem it appropriate to make the indicated changes, applicants should file a substitute specification.

Claims 1-16, 21-23 are examined in this Office action; claims 17-20, 24-27 are withdrawn from consideration.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 22 is drawn to an agent for "preventing" all of the following: prostatic cancer, prostatic hypertrophy, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea, breast cancer and pregnancy. First, there is no evidence that any of these can be successfully treated using LH-RH. Second, even if such evidence were provided for LH-RH *per se*, the question would then become which "derivatives" of LH-RH also can be used in this way. And even if this information were to be provided, that would not constitute evidence that "prevention" could be achieved. Prevention implies 100% success at eliminating even the appearance of symptoms of a disorder. If LH-RH were administered to each of 10,000 persons, and just one of them developed cancer, or became pregnant, such an experiment might be considered very successful. But it would not constitute evidence that prevention had been achieved. It is suggested that the term "preventing" be deleted.

The claim also recites the term "treating". While it is possible that some success has been achieved in the treatment of one or more of the foregoing disorders, there is no evidence of record that any of the recited disorders can be successfully treated. Nor is there guidance as to how to use the compositions for such purposes. Moreover, even if LH-RH *per se* is known to be effective for treating one or more of the recited disorders, it would not necessarily follow therefrom that a composition containing a hydroxynaphthoic acid salt of LH-RH in combination with a PLA/PLG copolymer will be as effective as the LH-RH *per se*. How often should be composition be administered for a given disease? How do the required dosages for the claimed composition differ from that of the LH-RH *per se*...? How advanced can the disease be before the patient's condition can no longer be improved by the claimed composition? When the claimed composition is administered to women, what is the frequency of pregnancy? Is the claimed composition effective as a contraceptive in men?

*

Claims 1-16, 21-23 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 is drawn to a "substance or a salt thereof". However, the term "substance" is sufficiently broad as to encompass salts. In traversing, applicants are requested to provide an example of a "salt" which is not also a "substance". Alternatively, it is suggested that the term "substance" be replaced with the term *compound*.

- The first word of each claim should begin with a capital letter.

- In claim 3, the term "LH-RH" may be used, if accompanied by the full name that this term represents.

- Claim 6 recites the following "according to claim 5 **above**". Here, the term "above" is superfluous.

- Claims 7 and 8 are not properly subgeneric to claim 6. Claim 6 mandates the presence of glycolic acid within the polymer. Claim 7, on the other hand, permits glycolic acid to be absent; claim 8 mandates that glycolic acid be absent.

- In claim 11, the appropriate "SEQ ID NO:" should be present.

- Claim 12 recites the following: "50-90 micromol per unit mass (gram)". Here the phrase "per unit mass" is superfluous.

- Claim 21 is drawn to "a pharmaceutical". First, how is this different form the composition of claim 1...? If there is no difference, it is suggested that claim 21 be cancelled. Alternatively, claim 21 should be written in independent form and drawn to a pharmaceutical *composition*.

- Claim 22 is drawn to "an agent for preventing or treating ... a contraceptive". Here, the term "contraceptive" has been grouped together with various diseases. From the perspective of §112, second paragraph, it is suggested that reference to contraceptive be made in a separate claim.

- Claim 22 is drawn to an agent which contains the composition of claim 3. How is the "agent" different from the composition? Are there additional ingredients present? It is suggested that claim 22 be written in independent form.

- Claim 23 is indefinite as to whether the hydroxynaphthoate salt or hydroxynaphthoate ester of the "bioactive substance" is intended.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the

basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 11-3, 5-16, 21-23 are rejected under 35 U.S.C. §102 (a) as being anticipated by Kamei (WO 98/32423).

Kamei discloses compositions comprising LHRH, PLA/PLG copolymer and 4, 4'-methylenebis (3-hydroxy-2-napthoic acid). Thus, the claims are anticipated.

There are two issues here. First, applicants' priority claim is noted. However, no translation of Japanese application 10-6412 has been provided, and so its contents cannot be determined. Second, there is the matter of what exactly is meant (in claim 1) by the phrase "**a** hydroxynaphthoic acid". Does this mean hydroxynaphthoic acid *per se*, or does it mean a compound that contains this moiety? As it happens, the compound 4, 4'-methylenebis (3-hydroxy-2-napthoic acid) does contain the moiety 3-hydroxy-2-napthoic acid. Of all the claims, only claim 3 actually requires that the hydroxynaphthoic acid-containing compound be limited to such. [It is suggested that applicants provide a translation of Japanese application 10-6412, or in the alternative, amend claim 1 to recite that 3-hydroxy-2-napthoic acid *per se* must be present in the composition].

*

The following is a quotation of 35 USC §103 which forms the basis for all obviousness

rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Conrow (USP 4,049,640).

Conrow discloses various ureylenebis- (carboxy-phenyleneazo)] bis [amino-hydroxy-naphthoic acids] and salts useful as complement inhibitors. Examples include 5, 5'-[Ureylenebis (2- carboxy-p-phenyleneazo)] bis [6-amino- 4- hydroxy- 2 - naphthoic acid], tetrasodium salt, and 4,4'-Ureylenebis [2- (2- amino- 8- hydroxy- 6-sulfo-1-naphthylazo)benzoic acid], tetrasodium salt. Also disclosed (col 11, line 44 is sustained release compositions, and (col 11, line 55) pharmaceutical compositions containing polymeric acids. Conrow does not employ the term "biodegradable polymer".

Thus, the ureylenebis- (carboxy-phenyleneazo)] bis- (amino-hydroxy- naphthoic acids) **are**

hydroxy- naphthoic acids; instant claim 1 does not specify which hydroxy- naphthoic acids are included. As such, the hydroxy- naphthoic acids of the reference serve the dual role of being the "biologically active substance" and the hydroxy- naphthoic acid. The claim is rendered obvious.

*

No claim is allowed.

Note that hydrogen atoms are missing on page 43

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800